

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 300—GENERAL

Subpart A [Reserved]

Subpart B—Combination Drugs

Sec.

300.50 Fixed-combination prescription drugs for humans.

Subpart C—Substances Generally Prohibited From Drugs

300.100 Chlorofluorocarbon propellants.

Subpart A [Reserved]

Subpart B—Combination Drugs

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 357, 360b, 361, 371.

§ 300.50 Fixed-combination prescription drugs for humans.

The Food and Drug Administration's policy in administering the new-drug, antibiotic, and other regulatory provisions of the Federal Food, Drug, and Cosmetic Act regarding fixed combination dosage form prescription drugs for humans is as follows:

(a) Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. Special cases of this general rule are where a component is added:

(1) To enhance the safety or effectiveness of the principal active component; and

(2) To minimize the potential for abuse of the principal active component.

(b) If a combination drug presently the subject of an approved new-drug application or antibiotic monograph has not been recognized as effective by the Commissioner of Food and Drugs based on his evaluation of the appropriate National Academy of Sciences-National Research Council panel re-

port, or if substantial evidence of effectiveness has not otherwise been presented for it, then formulation, labeling, or dosage changes may be proposed and any resulting formulation may meet the appropriate criteria listed in paragraph (a) of this section.

(c) A fixed-combination prescription drug for humans that has been determined to be effective for labeled indications by the Food and Drug Administration, based on evaluation of the NAS-NRC report on the combination, is considered to be in compliance with the requirements of this section.

[40 FR 13496, Mar. 27, 1975]

Subpart C—Substances Generally Prohibited From Drugs

§ 300.100 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human drugs as propellants in self-pressurized containers is generally prohibited except as provided by § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

PART 310—NEW DRUGS

Subpart A—General Provisions

Sec.

310.3 Definitions and interpretations.

310.4 Biologics; products subject to license control.

310.6 Applicability of "new drug" or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products.

Subpart B—Specific Administrative Rulings and Decisions

310.100 New drug status opinions; statement of policy.

310.103 New drug substances intended for hypersensitivity testing.

Subpart C—New Drugs Exempted From Prescription-Dispensing Requirements

310.200 Prescription-exemption procedure.

310.201 Exemption for certain drugs limited by new drug applications to prescription sale.